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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,588	03/30/2004	Gregory Donoho	LEX-0486-USA	4322

7590 10/27/2005

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,588

Applicant(s)

GREGORY DONOHO ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Applicants' preliminary amendment filed on March 30, 2004 is acknowledged. Amendment to the specification is acknowledged. Claims 1-5 have been canceled. New claims 6-21 have been added. Therefore, claims 6-21 are under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 6-17 drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding an amino acid sequence drawn from the group consisting of SEQ ID NOs: 2, 4 and 6, wherein said nucleic acid sequence comprising the nucleotide sequence of SEQ ID NOs: 1, 3 and 5; expression vectors; recombinant host cells, method of making said polypeptide; classified in class 435, subclass 69.1, 320.1, 252.3, 325; class 536, subclass 23.1, 23.5.

Should Group I be elected, applicants are required to select one nucleic acid sequence from SEQ ID NOs: 1, 3 and 5; and select one amino acid sequence from SEQ ID NOs: 2, 4 and 6. Each of the nucleic acids and encoded polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from the other. **This is not a species election.**
- II. Claims 18-21 drawn to an isolated polypeptide comprising an amino acid sequence drawn from the group consisting of SEQ ID NOs: 2, 4 and 6; classified in class 530, subclass 350, 300.

Should group II be elected, applicants are required to select one amino acid sequence from SEQ ID NOs: 2, 4 and 6. Each of the polypeptides have differing structure and function, therefore each sequence is patentably distinct, one from

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the other. **This is not a species election.**

The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP ' 806.04, MPEP ' 808.01). In the instant case the nucleic acids of Group I and the polypeptides of Group II differ with respect to their structure, and their physical, chemical and biological properties and function. The nucleic acids of Group I can be used for hybridization assay, while polypeptides of Group II can be used to make antibodies. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Lance Ishimoto on August 23, 2005, to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The

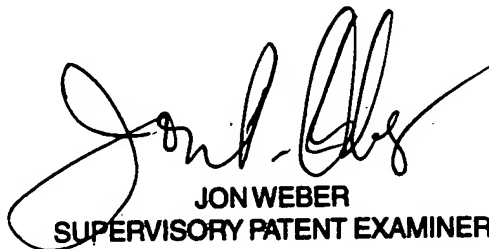
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examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

October 19, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER